

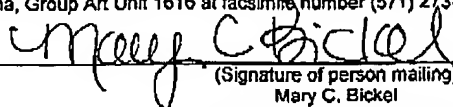
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Patent Application
Attorney Docket No. PC23199A

I hereby certify that this correspondence is being filed with the United States Patent and Trademark Office via facsimile to Examiner Lamm, Marina, Group Art Unit 1616 at facsimile number (571) 273-8300 on this 1st day of November 2005.

By



(Signature of person mailing)
Mary C. Bickel

(Typed or printed name of person)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF:

Steven W. Collier, et al.

Examiner: LAMM, MARINA

APPLICATION NO.: 10/636,013

Group Art Unit: 1616

FILING DATE: August 6, 2003

TITLE: STABLE NON-DIHYDRATE
AZITHROMYCIN ORAL SUSPENSIONS

Mail Stop Amendment
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

VIA FACSIMILE: (571) 273-8300 (4 Pages)

Sir:

**RESPONSE TO RESTRICTION AND SPECIES ELECTION
REQUIREMENTS**

In full response to the Office Action mailed September 9, 2005 requesting restriction of claims and election of species, Applicants respectfully submit the following amendments and remarks.

An Amendment in Response to the September 9, 2005 Office Action was originally due on October 9, 2005. Applicants hereby request a one-month extension of time, up to and including November 9, 2005 and the Commissioner is authorized to charge the \$120.00 fee for one-month extension of time to our Deposit Account No. 16-1445. Therefore, the present Amendment is being timely filed.

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Applicants hereby elect, with traverse, the powder for oral suspension of claims 1-28, for prosecution on the merits. Applicants also elect, with traverse, species (f). Applicants respectfully point out that claims 1, 16-28 read on the elected species.

Applicants respectfully urge that the aforesaid Restriction Requirement is improper, as it is far from clear that searching all of the claims constitutes an undue burden upon the office. For the same reasons, the Species Election Requirement is also improper if the Examiner does not continue to examine other species when he finds that the elected species is allowable.

Moreover, the Restriction Requirement and Species Election Requirement, if treated as a further restriction of claims, are contrary to public policy. Accordingly, modification and withdrawal of these requirements is respectfully requested.

The M.P.E.P. lists two criteria for proper restriction requirements. First, the inventions must be independent or distinct. M.P.E.P. § 803. Second, searching the additional invention must constitute an undue burden on the examiner if restriction is not required. *Id.* The M.P.E.P. directs the examiner to search and examine an entire application "if the search and examination of an entire application can be made without serious burden, even though it includes claims to distinct or independent inventions." *Id.*

Applicants respectfully urge that the present Restriction Requirement does not meet these criteria, since the powder for oral suspension of claims 1-28, although distinct, are closely related to the oral suspension of claims 29-56 and the methods of reducing non-dihydrate azithromycin form conversion of claims 57-67 (Group III claims), 68-74 (Group IV claims), 75 (Group V claim) and 76-78 (Group VI claims), respectively. The Species Election Requirement, if treated as a further restriction of claims, also does not meet these criteria because species (a) through (f), although distinct, are closely related to one another. Moreover, a search of powder for oral suspension of claims 1-28 will encompass all the six species of azithromycin conversion stabilizing excipients. Therefore, the examiner cannot establish that searching all the species would constitute an undue burden to the PTO.

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Further, it is respectfully urged that restricting the claims in the manner suggested in the September 9, 2005 office action and limiting the examination to species (f) will constitute an undue burden to applicants as well as the public. Hence, it is against public policy. If followed, the present Restriction Requirement and the Species Election Requirement would require applicants to file at least ten more applications directed to species (a) through (e) as well as to claims of Groups II through VI. The cost of prosecuting and maintaining these applications, and any patents which may issue therein, is unreasonable in view of the fact that the application contains only 78 claims.

In view of the foregoing, reconsideration and modification of the Restriction Requirement is respectfully requested. In addition, applicants respectfully request that the Examiner continue to examine species (a) through (e) if the claims reading on species (f) are found allowable. Applicants note that M.P.E.P. 803.02 requires that "If the elected species is allowable, the search will be extended to other species."

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CONCLUSION

In view of the remarks, reconsideration of the restriction and species election requirements are respectfully requested.

It is believed that no fee, other than the \$120.00 one-month extension of time fee, is required in connection with the filing of the present Response. However, if any other fees are required, the Commissioner is authorized to charge such fees to our Deposit Account No. 16-1445.

Respectfully submitted,

Date: Nov. 1, 2005

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